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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/695,919 | 10/26/2000 | Martin Gerl | 02481.1704 | 4319 |

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[REDACTED] EXAMINER

CHEU, CHANGHWA J

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1641

DATE MAILED: 01/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/695,919 | GERL ET AL. |
| | Examiner Jacob Cheu | Art Unit 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 April 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

(a) Trademark

The use of BIACore® in page 33, line 4, have been noted in this application. This should be capitalized wherever they appear and be accompanied by the generic terminology if applicable. Although the use of trademark is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademark. Appropriate correction is required.

(b) Deposit

The specification (page 5) is rejected to as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited. The instant invention is to use antibodies for the determining a c-peptide-containing impurities in a sample. It is not clear whether the claimed antibodies are either monoclonal, polyclonal, or both. If the claimed antibodies are monoclonal antibodies, then an adequate hybridoma cell line producing such monoclonal antibodies must be available. Clearly, without access to a hybridoma cell line producing claimed monoclonal antibody, it would not be possible to practice the claimed invention. Therefore, a suitable deposit for patent purposes is suggested.

v

Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the claimed antibodies is an unpredictable event. Therefore, it is deemed to require undue experimentation for reproduce the claimed antibodies species.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of the deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Claim Rejections - 35 USC § 112

2. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as lack of enablement for the reasons set forth in the specification. (See (b) Deposit)

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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With respect to claim 1, the wording "derivative" is vague and indefinite. It is unclear what applicants refer to the "derivative." For instance, whether applicants mean chemical addition, i.e. glycosylation, methylation, or phosphorylation. Or, alternatively, applicants mean the derivative generated from the recombinantly produced human insulin, such as various fragments or polypeptides. In this situation, there is no need to specify "derivative" since recombinant technique inherently embraces different fragments of interests.

Similarly, claim 2 shares the same problem as claim 1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 are rejected under 35 U.S.C. 102 (b) as being anticipated by Hara et al. (EP 0484961).

Hara et al. teach measuring human C-peptide containing sample by contacting the sample with antibody specifically recognizing the C-peptide and a tracer C-peptide for competitive assay, and a labeled antibody for determining the immunoreaction product. (See claims 1-7). Hara et al. also teach the process conducted with dilution buffer at pH value of 9.5 which is "about 9.0" read on the instant claim 3. (See page 4, Example 1 (C)) However, Hara et al. does not explicitly teach using a sample of recombinantly produced human insulin or a derivative for its assay. Nevertheless, Examiner takes the position that the recombinant produced human insulin as a product, in the absence of contrary evidence, i.e. comparison or unexpected

properties, is identical or only slightly different from the nature human insulin. In *Ex Parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) Therefore, the process taught by Hara et al., inherently encompass the instant claim. Thus, Hara et al. anticipate the instant claims 1-3.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hara et al., as applied to claims 1-3, and further in view of Campbell (section 1.3.4. page 29; Monoclonal Antibody Technology (1984) Elsevier Science Publishers) in combination with Naithani et al. (Fed. Rep. Ger. International Congress Series (1979) 468: 94-98)

Hara et al. reference has been discussed but is silent in teach deriving antibodies recognizes monkey C-peptide. Campbell teaches that “*it is customary now for any group working on a macromolecule to both clone the genes coding for it and make*

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monoclonal antibodies to it- sometimes without a clear objective for their application." (See ch. 1, section 1.3.4. page 29). Naithani et al. teach syntheses of *monkey C-peptide* and its derivatives. (See abstract) It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the conventional method of producing antibody as suggested by Campbell once the peptide of interest is available as taught by Naithani et al. since it is considered a "customary practice" in the art to make specific antibody recognizing the particular peptides.

Conclusion

10. No claim is allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner



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January 27, 2003


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

